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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,220	09/17/2003	Gul Balwani	2286.0330000/BJD	6274
26111 7590 02/06/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER CARTER, KENDRA D	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			02/06/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/665,220

**Applicant(s)**

BALWANI ET AL.

**Examiner**

Kendra D. Carter

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/17/03
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-9, in the reply filed on November 19, 2007 is acknowledged. The traversal is on the ground(s) that Groups I and II are related and would not place a serious burden on the Examiner to search. This is not found persuasive because the method of use in composition claims do not receive patentable weight. Thus, the claimed composition can be used for asthma instead of to treat cough and nasal congestion. Additionally, while the searches of Group I and II may be overlapping, there is no reason to believe that the searches would be coextensive. In searching Group I, Examiner will be focusing on the patentability of the composition itself, and not the method of treating and relieving the distress of cough and nasal congestion of Group II. Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of treatment and not the composition itself.

Claims 10-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group of claims, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 7-10 of U.S. Patent No. 6,462,094 B1 ('094) in view of Venkataraman (US 6,509,492 B1).

The US Patent '094 teaches a therapeutic composition for the symptomatic relief of cough comprising pharmaceutically effective amounts of active ingredients consisting of phenylephrine tannate and guifensin in tablet or suspension form (see claims 1-3). The amounts of phenylephrine tannate can be from about 20 to 30 mg, about 25 mg,

about 3 to 8 mg, about 5 mg, and the amounts of guaifenesin can be from about 100 to 300 mg, about 200 mg, about 50 to 150 mg and about 100 mg, per 5 mL of suspension (see claims 7-10).

'094 does not teach pyrilamine tannate or its amounts.

Venkataraman teaches a tannate composition comprising an antihistamine, an antitussive and an expectorant such as pyrilamine tannate, phenylephrine tannate and guaifenesin tannate to treat cough and cold symptoms (see abstract; columns 6 and 7, table 1; and column 10, line 9-10).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of '094 and an expectorant such as pyrilamine tannate because it is known in the art to combine an expectorant with an antihistamine and an antitussive agent to treat coughs and colds.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 6,509,492 B1).

Venkataraman teaches composition for treating upper respiratory indications, such as cough, cold, cold-like symptoms and symptoms related to upper respiratory infections comprising combinations of at least one or more agents into a single administrative dose (see abstract), such as the an antihistamine, an antitussive and an expectorant (see column 10, lines 9-10). Antihistamines include pyrilamine tannate; decongestants include phenylephrine tannate; and expectorants include guaifensin tannate (see columns 6 and 7, table 1; addresses claim 1). Suggested dosage amounts are not to be seen as limiting and are given in standard molecular compounds that would be converted to equivalent tannate compounds (see column 8, lines 36-40). Pyrilamine maleate is from 25-50 mg with a maximum daily dose of 200 mg; phenylephrine HCl has an oral dose of 10 mg and a maximum daily dose of 60 mg; and guaifenesin is from 200-400 mg with a maximum dose of 2400 mg (see columns 8 and 9, table 2; addresses claims 3-5 and 7-9). The composition can be in the form of a suspension or tablet (see column 2, lines 5-6; addresses claims 2 and 6).

Venkataraman does not specifically teach the exact amounts of each compound as disclosed in claims 3-5 and 7-9.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Venkataraman and the amounts of each compound as disclosed in claims 3-5 and 7-9 because Venkataraman teaches a range that either overlaps or is close to the Applicant's amounts. In regards to the amounts of Venkataraman that are close the Applicant's amounts, the following teaching and note provides motivation and obviousness to the Applicant's amounts of each compound: 1) the Applicant's claim language "about"; 2) the suggested dosage amounts provided by Venkataraman are not to be seen as limiting (see column 8, lines 36-40); 3) maximum dosages for both adults and children are given by Venkataraman (see columns 8 and 9, table 2), which means that the hourly dosage can be adjusted depending on the type of person being treated and as well as the hourly dosage is within the maximum dosage limit; and 4) it is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

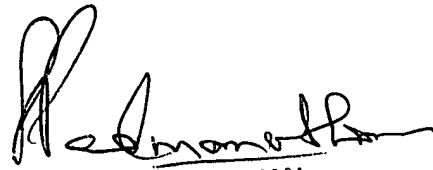
**Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

  
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